

(12) PATENT ABRIDGMENT (11) Document No. AU-B-11602/88  
(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 603862

(54) Title  
PLASTIC CARTRIDGE AND SYRINGE

International Patent Classification(s)  
(51)\* A61J 001/06 A61M 005/24

(21) Application No. : 11602/88

(22) Application Date : 10.02.88

(43) Publication Date : 10.08.89

(44) Publication Date of Accepted Application : 29.11.90

(71) Applicant(s)  
ASTRA PHARMACEUTICALS PTY. LTD.

(72) Inventor(s)  
MICHAEL BROWNING KIMBER; FRANK ALEXANDER POPOVSKY

(74) Attorney or Agent  
PHILLIPS ORMONDE & FITZPATRICK, 367 Collins Street, MELBOURNE VIC 3000

(56) Prior Art Documents  
AU 41625/78 A61M 5/18 5/32-  
AU 509664 23835/77 A61M 5/18 5/315  
AU 451768 18937/70 A61J 1/06

(57) Claim

1. A plastic cartridge for use as a pre-filled cartridge in a syringe comprising a hollow cylindrical barrel having a top end and a bottom end both of which are open wherein said bottom end is sealed by a stopper and said top end is covered by a plastic cap and adapted to be sealed by the said plastic cap, said cap including a top having an integral central portion of relatively thin cross section which may be punctured by the reverse end of a double sided needle so to allow ejection of the contents of the cartridge, and wherein said cap and said top end of the cartridge barrel are adapted to be welded one to the other so to enable sealing connection therebetween.

14. A method for manufacturing a plastic pre-filled syringe cartridge which comprises:-

- (i) injection moulding a cartridge barrel having a top end and a bottom end both of which are open in an aseptic environment;
- (ii) injection moulding a plastic cap having an integral central portion of relatively thin cross section which may be punctured by a double sided needle;

(11) AU-B-11602/88  
(10) 603862

-2-

- (iii) introducing into the aseptic environment a pre-sterilized stopper;
- (iv) fitting the pre-sterilized stopper into the bottom end of the cartridge barrel in the aseptic environment;
- (v) aseptically filling the said cartridge with an injectable medium in said aseptic environment sealingly; and
- (vi) welding said cap to the top end of the cartridge barrel in the aseptic environment.

INSTRUCTIONS  
(a) If Convention application insert "Convention"

603862  
AUSTRALIA

Patents Act

APPLICATION FOR A (b) STANDARD ~~XXXX~~ PATENT

(b) Delete one

(c) Insert FULL name(s) of applicant(s)

1/We (c) ASTRA PHARMACEUTICALS PTY. LTD.

(d) Insert FULL address(es) of applicant(s)

of (d) 10-14 Khartoum Road,  
North Ryde,  
Sydney 2113,  
Australia

(e) Delete one

(f) Insert TITLE of invention

hereby apply for the grant of a (e) Standard ~~XXXX~~ Patent for an invention entitled

(f) PLASTIC CARTRIDGE AND SYRINGE

which is described in the accompanying (e) complete specification.

(g) Insert "complete" or "provisional" or "petty patent"

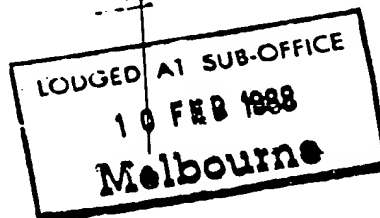
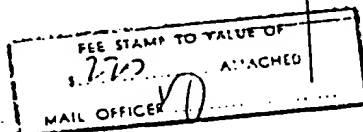
(Note: The following applies only to Convention applications)

Details of basic application(s)

Application No.

Country

Filing Date



Address for Service:

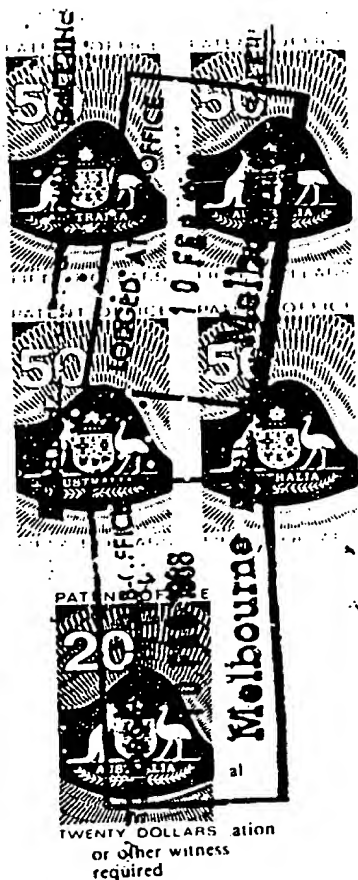
PHILLIPS ORMONDE AND FITZPATRICK  
Patent and Trade Mark Attorneys  
367 Collins Street  
Melbourne, Australia 3000

ACCEPTED AND AMENDMENTS

Dated (i) 10 February, 1988

(j) PHILLIPS ORMONDE & FITZPATRICK  
Attorneys for:  
ASTRA PHARMACEUTICALS PTY. LTD.

(k)



PHILLIPS ORMONDE AND FITZPATRICK  
Patent and Trade Mark Attorneys  
367 Collins Street  
Melbourne, Australia

# AUSTRALIA

Patents Act

## DECLARATION FOR A PATENT APPLICATION

### INSTRUCTIONS

- (a) Insert "Convention" if applicable  
(b) Insert FULL name(s) of applicant(s)

- (c) Insert "of addition" if applicable  
(d) Insert TITLE of invention

- (e) Insert FULL name(s) AND address(es) of declarant(s) (See headnote\*)

- (f) Insert FULL name(s) AND address(es) of actual inventor(s)

- (g) Recite how applicant(s) derive(s) title from actual inventor(s) (See headnote\*\*)

- (h) Insert country, filing date, and basic application(s) for the/or EACH basic application

- (k) Insert PLACE of signing

- (l) Insert DATE of signing

- (m) Signature(s) of declarant(s)

Note: No legalization or other witness required

In support of the (a) application made by  
(b) ASTRA PHARMACEUTICALS PTY. LTD.

(hereinafter called "applicant(s) for a patent (c)  
invention entitled (d)

PLASTIC CARTRIDGE AND SYRINGE

I/We (e) Ian Mertell of 35 Eastgate Avenue,  
Killara, New South Wales 2071,  
Australia

do solemnly and sincerely declare as follows:

1. ~~XXXXXX~~ (or, in the case of an application by a body corporate)  
I am ~~XXXXXX~~ authorized to make this declaration on behalf of the applicant(s).
2. ~~XXXXXX~~ (or, where the applicant(s) is/are not the actual inventor(s))  
Frank Alexander Popovsky of , 11 Patterson St., Tahmoor NSW 2573

and Michael Browning Kimber of 5 Mariana Close, St. Ives NSW 2075

is/are the actual inventor(s) of the invention and the facts upon which the applicant(s)  
is/are entitled to make the application are as follows:

- (k) The applicant is the assignee of the invention  
from the said actual inventors

(Note: Paragraphs 3 and 4 apply only to Convention applications)

3. The basic application(s) for patent or similar protection on which the application is based  
is/are identified by country, filing date, and basic applicant(s) as follows:

(h)

4. The basic application(s) referred to in paragraph 3 hereof was/were the first application(s)  
made in a Convention country in respect of the invention the subject of the application.

Declared at (k)

Dated (l)

(m)

To: The Commissioner of Patents

PHILLIPS ORMONDE & FITZPATRICK  
Patent and Trade Mark Attorneys  
367 Collins Street  
Melbourne, Australia

## INSTRUCTIONS

- (a) If Convention application insert "Convention"

AUSTRALIA

Patents Act 1990

APPLICATION FOR A (b) STANDARD/~~PETTY~~ PATENT

(b) Delete one

(c) Insert FULL name(s) of applicant(s)

I/We (c) ASTRA PHARMACEUTICALS PTY. LTD.

(d) Insert FULL address(es) of applicant(s)

of (d) 10-14 Khartoum Road,  
North Ryde,  
New South Wales,  
Australia

(e) Delete one

hereby apply for the grant of a (e) Standard/~~Patent~~ Patent for an invention entitled

(f) Insert TITLE of invention

(f) PLASTIC SYRINGE

(g) Insert "complete" or "provisional" or "petty patent"

which is described in the accompanying (g) Provisional specification.

(Note: The following applies only to Convention applications)

Details of basic application(s)

(h) Insert number, country and filing date for the/or each basic application

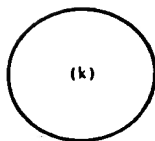
	Application No.	Country	Filing Date
(h)			

Address for Service:

PHILLIPS ORMONDE AND FITZPATRICK  
Patent and Trade Mark Attorneys  
367 Collins Street  
Melbourne, Australia 3000

(i) Insert date of signing

Dated (i) 15 January, 1991

(j) Signature of applicant(s)  
(For body corporate see headnote\*)

(k)

(j) PHILLIPS ORMONDE & FITZPATRICK  
Attorneys for:  
ASTRA PHARMACEUTICALS PTY. LTD.

(k) Corporate seal if any

Note: No legalization or other witness required

PHILLIPS ORMONDE AND FITZPATRICK  
Patent and Trade Mark Attorneys  
367 Collins Street  
Melbourne, Australia

AUSTRALIA

603862

Patents Act

# COMPLETE SPECIFICATION

(ORIGINAL)

Class

Int. Class

Application Number:

Lodged:

This document contains the amendments made under section 49 and is correct for printing.

Complete Specification Lodged:

Accepted:

Published:

Priority

Related Art:

APPLICANT'S REF.: 929-1

Name(s) of Applicant(s): ASTRA PHARMACEUTICALS PTY. LTD.

Address(es) of Applicant(s): 10-14 Khartoum Road,  
North Ryde,  
Sydney 2113,  
Australia

Actual Inventor(s): MIKE KIMBER

Address for Service is:

PHILLIPS, ORMONDE AND FITZPATRICK  
Patent and Trade Mark Attorneys  
367 Collins Street  
Melbourne, Australia, 3000

Complete Specification for the invention entitled:

PLASTIC CARTRIDGE AND SRYINGE

The following statement is a full description of this invention, including the best method of performing it known to applicant(s):

This invention relates to a plastic cartridge for use as a prefilled plastic cartridge. The cartridge of the invention can be used in conjunction with a finger grip, a plunger rod and a hypodermic needle as a syringe or can be used in place of a conventional cartridge in a syringe barrel.

Many syringes in common use today utilize a glass or plastic pre-filled cartridge. Such cartridges are conventionally sealed at one end by a rubber stopper and at the other end by a rubber membrane which is sealed against the outside of the glass cartridge by a metal cap. The metal cap is crimped onto the end of the cartridge thus ensuring an effective seal at the end of the cartridge remote from the rubber stopper. One example of such a syringe is described in AU-A-73632/81.

Cartridges of the type described are conventionally filled with an injectable medium and may be then autoclaved to ensure the sterility of the contents. In use, these cartridges are inserted into a syringe holder designed to allow expression of the contents of the cartridge. For example, metal barrelled syringes having a fitting at one end to accept a double sided needle and a plunger at the other end have previously been in use. These syringes are intended for multiple use and must be stored in a sterilizing cabinet after each use. Furthermore, they suffer from the disadvantage that they are heavy and large. The size of the syringe is a particular disadvantage as these syringes are intimidating for patients. Also in use are disposable syringe bodies to which there is fixed a double sided

needle. When these disposable syringe bodies are used a pre-sterilized cartridge is inserted into the syringe body. The double sided needle is adapted to puncture the rubber membrane at the end of the cartridge barrel and a plunger rod is used to expel the contents of the cartridge.

The object of the present invention is to provide a pre-filled plastic cartridge which can be used in existing syringe bodies or preferably be used as a component part of a disposable syringe unit.

In accordance with the present invention there is ~~provided a plastic pre-filled cartridge. The cartridge~~ comprises a hollow cylindrical barrel which is open at both ends. This barrel is sealed at one end (the bottom end) by a stopper and at the other end (the top end) by a plastic cartridge cap.

The barrel may be made of any rigid plastics material. For example, a translucent or transparent plastics material such as polyethylene terephthalate, polyamide, polypropylene or TPX may be used. Other suitable materials are well known to those skilled in the art. Most preferably, polypropylene is used as this material is of relatively low cost, has a clear finish and is a well tested material for containing pharmaceutical substances.

At the top end of the barrel, there is preferably provided a neck portion having a diameter smaller than the diameter of the major portion of the cartridge barrel. At the end of the neck portion there is preferably provided an upper annular face, an outer neck wall and an abutment ~~shoulder. These surfaces may be constituted by a flange~~





provided a plastic cartridge for use as a pre-filled cartridge in a syringe comprising a hollow cylindrical barrel having a top end and a bottom end both of which are open wherein said bottom end is sealed by a stopper and said top end is covered by a plastic cap and adapted to be sealed by the said plastic cap, said cap including a top having an integral central portion of relatively thin cross section which may be punctured by the reverse end of a double sided needle so to allow ejection of the contents of the cartridge, and wherein said cap and said top end of the cartridge barrel are adapted to be welded one to the other so to enable sealing connection therebetween.

The barrel may be made of any rigid plastics material. For example, a translucent or transparent plastics material such as polyethylene terephthalate, polyamide, polypropylene or TPX may be used. Other suitable materials are well known to those skilled in the art. Most preferably, polypropylene is used as this material is of relatively low cost, has a clear finish and is a well tested material for containing pharmaceutical substances.

At the top end of the barrel, there is preferably provided a neck portion having a diameter smaller than the diameter of the major portion of the cartridge barrel. At the end of the neck portion there is preferably provided an upper annular face, an outer neck wall and an abutment shoulder. These surfaces may be constituted by a flange



provided on the cartridge neck and may be in the form of a circumferential ring or rib.

The cartridge barrel is sealed at the bottom end by a stopper. The stopper may be of any known type and has an inner face facing internally into the cartridge body and an outer face facing out of the cartridge body. Preferably the stopper is a resilient stopper and may be made from a rubber compound. Preferably the stopper has at least two circumferential sealing rings to assist in maintaining a fluid tight seal at the bottom end of the cartridge barrel. The stopper preferably also has a plunger retaining recess situated in its outer face. This recess is preferably centrally located in the end of the stopper.

The cartridge cap is also made of a plastics material and preferably comprises a top and a depending peripheral skirt. A central portion of the top of the cap is of relatively thin cross-section so that it may be easily punctured. The peripheral skirt is rigid and adapted to fit over the top end of the cartridge barrel. The cap is sealingly affixed to the cartridge barrel by welding the cap to the top end of the cartridge barrel.

Preferably the cartridge barrel has a neck portion and a flange on the neck portion. In such an embodiment the peripheral skirt on the cartridge cap is desirably adapted to clip over the top of the flange on the neck of the cartridge barrel so to retain the cap firmly in place over the top end of the barrel. Once in place, the depending peripheral skirt is preferably in contact with the outer neck wall on the neck of the cartridge and the bottom of the peripheral skirt is

clipped over and is in contact with the abutment shoulder on the neck. The cap may also have an annular shoulder located on the inside of the peripheral skirt to clip over the flange on the neck of the cartridge barrel. The cap may be welded to the cartridge barrel neck.

In one embodiment of the invention the cartridge cap is also provided with an annular rib on the underside of the top of the cap. In this embodiment the cap is fitted onto the top of the cartridge barrel and is then ultrasonically welded to the barrel. Preferably the annular rib is located to abut against the upper annular face on the end of the neck of the cartridge barrel. By applying the horn and anvil of the ultrasonic welder on opposite sides of the annular rib the rib is caused to soften thus providing the material to form a sealing ring between the cartridge cap and barrel. Alternatively, the cartridge cap may be contact or otherwise butt welded to the cartridge barrel.

The cap may be made of any suitable plastics material but is preferably made of an elastomer such as polypropylene or polyethylene.

In another embodiment of the invention the cartridge cap has an integrally moulded needle fitting above the sealing area. Preferably this fitting is of standard configuration such as a screw thread fitting as often used by dentists or a luer slip or luer lock arrangement. This fitting is hollow and the cartridge barrel is sealed by the relatively thin puncturable top section of the cap provided beneath the needle fitting.

Optionally, an overcap is also provided. Such an

overcap is useful in keeping the cap protected from undue interference whilst the cartridge is not in use. Such an overcap is employed primarily however to protect the end of the cartridge from becoming contaminated by micro-organisms.

The cartridge described above in any of its embodiments can be used in existing syringe barrels (with the necessary modifications) or can itself be used when fitted with a cap having a needle fitting as a component part of a syringe unit.

Where used as a component part of a syringe unit it is necessary that the cartridge be fitted with a finger grip. Preferably the finger grip is a plastic sleeve shaped component having a flange sufficiently wide for accommodating a finger on either side of the cartridge barrel. Such a finger grip is also preferably made of an elastomer such as polypropylene, polyethylene or polyethylene terephthalate. The finger grip is adhered to the side of the cartridge, preferably by welding same to the plastic cartridge barrel.

In the total syringe unit it is also necessary to have a plunger rod. The plunger rod may have a variety of moulded ends, such as a screw thread to allow positive aspiration; or a blunt end to allow self aspiration during injection.

In use the cartridge/syringe unit is assembled by inserting the plunger rod into the stopper sealing the bottom end of the cartridge.

The overcap, if present, is removed to reveal the needle fitting on the cartridge cap. A double-sided needle having a corresponding fitting to that moulded onto the cartridge cap is used. As the hypodermic needle is attached to the needle fitting on the cartridge cap the inner end of

the hypodermic needle bears against the relatively thin top wall of the cap and upon application of sufficient force punctures the relatively thin top wall providing access to the contents of the cartridge barrel so to allow ejection of its contents.

Application of a force against the plunger rod causes positive forward movement of the stopper in the cartridge barrel thus causing expression of the injectable through the hypodermic needle. In this form there is provided an all plastic (other than cannula) hypodermic syringe which is easy to use and which is disposable after a single use.

A preferred embodiment of the invention is hereafter described with reference to the following drawings in which:

Figure 1 is a cross-sectional exploded view of a cartridge made in accordance with the present invention.

Figure 2 is a cross-sectional exploded view of a cartridge made in accordance with the present invention having a screw threaded needle fitting and overcap.

Figure 3 is a cross-sectional exploded view of a syringe unit utilizing the cartridge shown in Figure 2.

Figure 4 is a cross-sectional assembled view of a syringe unit utilizing the cartridge shown in Figure 2.

~~Figure 5 is a cross sectional exploded view of a cartridge made in accordance with the present invention having a luer slip needle fitting.~~

In Figure 1 there is shown a cartridge barrel 1. Cartridge barrel 1 is made of a plastics material, most preferably polypropylene. At the bottom end of barrel 1 ~~there is an open end 2 into which there is inserted a stopper~~

Figure 5 is a cross-sectional view of a cartridge cap having a screw-type needle fitting with an attached hypodermic needle.

Figure 6 is a cross-sectional exploded view of a cartridge made in accordance with the present invention having a luer slip needle fitting.

In Figure 1 there is shown a cartridge barrel 1. Cartridge barrel 1 is made of a plastics material, most preferably polypropylene. At the bottom end of barrel 1 there is an open end 2 into which there is inserted a stopper



Stopper 3 is adapted to move within barrel 1 whilst maintaining a fluid tight seal. To this end, stopper 3 is preferably made of rubber and has two sealing rings 3a and 3b. At its top end cartridge barrel 1 has a neck 4 of smaller diameter than the rest of the cartridge barrel body. At the end of neck 4 there is provided a flange 5. The cartridge barrel 1 is open at the top end at open end 6.

A cap 7 is provided, which is adapted to be welded to the top end of neck 4 of cartridge barrel 1. This cap has an annular rib 8 adapted to clip over flange 5 on neck 4. A circumferential rib 10 is provided on the underside of the top 11 of cap 7 and is located so that it abuts against the top of neck 4 when the cartridge cap 7 is clipped onto the top of cartridge barrel 1. A relatively thin central portion of the top of the cap forms part of the top of cap 7. The top of the cap 7 extends across the top of open end 6. The thin central portion is integral with the rest of cap 7.

In figure 2 there is illustrated a cartridge having a similar barrel 1 and stopper 3 as that illustrated in figure 1. ~~Cap 7 is again provided with a relatively thin puncturable~~ portion 9. However in this embodiment a needle fitting 12 is also provided on cartridge cap 7. This needle fitting is a standard screw threaded needle finish and is adapted to receive a double sided needle having a corresponding screw thread finish.

Assembly of the cartridge is preferably as follows. The cap 7 and overcap 23 are injection moulded from sterile plastic material, the injection moulding machine being situated in an aseptic area. ~~Cartridge barrel 1 is stoppered~~

1. Cartridge cap 7 is shown in greater detail in the enlargement "A" to Figure 2. Cap 7 is again provided with a relatively thin puncturable portion 9. However in this embodiment a needle fitting 12 is also provided on cartridge cap 7. This needle fitting is a standard screw threaded needle finish and is adapted to receive a double sided needle having a corresponding screw thread finish. This is illustrated in Figure 5 where a hypodermic needle 12a is shown once fitted onto needle fitting 12.

Assembly of the cartridge is preferably as follows. The cap 7 and overcap 23 are injection moulded from sterile plastic material, the injection moulding machine being situated in an aseptic area. Cartridge barrel 1 is stoppered



with a pre-sterilized stopper 3 at open end 2 and is then aseptically filled. After the cartridge has been filled the cap 7 is clipped onto neck 4, rib 8 seating beneath flange 5. A fluid tight seal is ensured by welding cap 7 to cartridge barrel 1. In the embodiment shown this is effected by ultrasonic welding. A welding horn is placed on top 11 above circumferential rib 10 and a welding anvil is placed under the bottom lip 14 of depending peripheral skirt 13. Ultrasonic welding causes circumferential rib 10 to soften and form a sealing ring with the top of neck 4.

The cartridge illustrated in figure 1 can simply be used as a replacement for existing cartridges in re-useable or disposable syringe barrels. The relatively thin central cap portion 9 can be punctured by a double sided needle providing access to the injectable medium contained within the cartridge.

The cartridge illustrated in figure 2 can be used in syringe assemblies which are presently available (with minor adjustments to the top end of the assembly to accommodate the cartridge cap with needle finish) or as a component in a disposable syringe unit. The contents of the cartridge shown in figure 2 are revealed for injection by screwing a double sided hypodermic needle <sup>(similar to that shown as 12a in figure 5)</sup> ~~(not shown)~~ having a corresponding screw thread finish onto the cap needle finish 12. As the hypodermic needle is screwed onto the needle finish 12 the inner needle punctures the relatively thin central portion 9 providing access to the contents of the cartridge barrel.

A disposable syringe unit utilizing the cartridge illustrated in figure 2 is shown in an exploded view in



figure 3.

Cartridge barrel 1 and cap 7 are illustrated in figure 2. A finger grip 15 is provided at the bottom end of the cartridge body 1. The finger grip 15 has a hollow sleeve 16 shaped to fit over the end of cartridge barrel 1. The finger grip may be adhered to the cartridge barrel 1 but is preferably welded thereto. Finger grip 15 is provided with an arm 17 which protrudes over opposite sides of sleeve 16 to provide a gripping area 18 on either side of cartridge barrel 1. A plunger rod 19 is also provided and has a moulded end 20 adapted to fit into a recess 21 provided in stopper 3. A handle 22 is located at the end of plunger rod 19 so to enable pressure to be applied to plunger rod in the axial direction of the cartridge barrel 1. A protective cap 23 is provided at the top end to fit over and protect the cap 7.

Figure 4 shows the above described syringe unit in an assembled condition. As illustrated cap 7 is clipped onto the neck 4 of cartridge barrel 1. Overcap 23 is clipped over the top of cap 7 and neck 4. Finger grip 15 is affixed to the end of cartridge barrel 1 and plunger rod 19 is inserted into the recess 21 provided in the end of stopper 3.

In use, hypodermic needle once fitted, sealingly screws onto the screw thread finish on cap 7 and positive pressure on plunger rod 19 causes stopper 3 to advance in cartridge barrel 1 causing the injectable medium to be expressed through the hypodermic needle (not shown).

In figure 6 there is illustrated a syringe unit which is the same in all respects as that illustrated in figure 3 except that a different needle fitting is moulded onto cap

7. In this embodiment a luer slip needle fitting is moulded into cap 7. In the same way a relative thin central portion is provided across the open end of cartridge barrel 1 to ensure that the contents of the cartridge cannot flow through to the needle fitting.

In each of the embodiments described herein it is possible using the cartridge of the present invention to provide a disposable syringe which is easy to use and simple in application. There is no need to use a separate syringe holder and the cartridge can be provided to practitioners in a partially assembled condition with the finger grip already attached to the cartridge barrel. The only separate components being a plunger rod and a standard double sided hypodermic needle.

Each of the above mentioned embodiments can be either partially or completely manufactured in an aseptic environment to ensure the sterility of the injectable medium. For example in the embodiment illustrated in figure 3, cartridge barrel 1 is preferably injection moulded in an aseptic environment. Stopper 3 is then delivered to the aseptic environment in a pre-sterilized condition and inserted into the bottom end 2 of cartridge barrel 1. The cap 7 is also preferably injection moulded in an aseptic environment. The cartridge barrel is stoppered then filled with the pre-sterilized injectable medium and is then capped by the injection moulded cartridge cap 7. The cap 7 is then welded to cartridge barrel 1. This is preferably done by ultrasonic welding. Overcap 23 is also preferably injection moulded in the aseptic environment and is fitted over the cap

7 and neck 4 prior to removal of the cartridge from the aseptic conditions. When manufactured as described above it is important that the polymer beads used for the injection moulding process be pre-sterilized prior to injection moulding of the component parts of the cartridge. Finger grip 15 and plunger rod 18 can be injection moulded outside of the aseptic environment as they are not placed in direct contact with the injectable medium.

The cartridge described above represents a unique product for use in delivering injectable substances. It provides many improvements over the cartridges in present use. In particular, the cartridge described does not suffer through use of multiple components such as metal caps and rubber membranes. Assembly of the cartridge described is simpler and the cartridge is easier to use, store and manufacture. The use of one cap also provides a more satisfactory seal than the combination metal rubber counterpart.

Further, the cartridge when supplied with a cap having a needle fitting attached thereto can be used in a simple disposable pre-filled syringe unit which is not as heavy, large or intimidating as existing syringes.

Finally, it is to be understood that various alterations, modifications and/or additions may be introduced into constructions and parts previously described without departing from the spirit or ambit of the invention.

The Claims defining the invention are as follows:-

1. A plastic cartridge for use as a pre-filled cartridge in a syringe comprising a hollow cylindrical barrel having a top end and a bottom end both of which are open wherein said bottom end is sealed by a stopper and said top end is covered by a plastic cap and adapted to be sealed by the said plastic cap, said cap including a top having an integral central portion of relatively thin cross section which may be punctured by the reverse end of a double sided needle so to allow ejection of the contents of the cartridge, and wherein said cap and said top end of the cartridge barrel are adapted to be welded one to the other so to enable sealing connection therebetween.
2. A plastic cartridge as claimed in claim 1 wherein the top end of the barrel has an upper annular face and wherein an annular rib is provided on the underside of the top of the cap and located so to abut against the upper annular face of the barrel after application of the cap onto the top end of the barrel and adapted to form a sealing ring between the underside of the top of the cap and the upper annular face when the cap is welded to the cartridge barrel.
3. A plastic cartridge as claimed in claim 1 wherein the top end of the barrel has an upper annular face and wherein an annular rib is provided on the said upper annular face and located so to abut against the underside of the top of the cap after application of the cap onto the top end of the cartridge barrel and adapted to form a sealing ring between the underside of the top of the cap and the upper annular face when the cap is welded to the cartridge barrel.
4. A plastic cartridge as claimed in any one of the previous claims wherein the cap has integrally moulded



thereto a needle fitting adapted to receive a hypodermic needle.

5. A plastic cartridge as claimed in claim 4 wherein the needle fitting moulded onto the cartridge cap is any one of a luer slip, luer lock or screw thread fitting.

6. A plastic cartridge as claimed in any one of the previous claims wherein said cap comprises a depending peripheral skirt, said depending peripheral skirt being adapted to fit over the top end of the cartridge barrel.

7. A plastic cartridge as claimed in any one of the previous claims wherein said top end of the cartridge barrel has a neck portion having a diameter smaller than the diameter of the major portion of the cartridge barrel.

8. A plastic cartridge as claimed in claim 7 wherein said neck portion comprises a flange and said cap is adapted to clip over the flange so to retain the cap firmly in place over the top end of the barrel.

9. A plastic cartridge as claimed in claim 8 wherein said cap has an annular shoulder located on the inside of the peripheral skirt adapted to clip over the flange on the said neck portion of the cartridge barrel.

10. A plastic cartridge as claimed in claim 9 wherein said neck portion comprises an upper annular face, an outer neck wall and an abutment shoulder such that upon placement of the cap onto the top end of the cartridge barrel the annular shoulder located on the inside of the peripheral skirt of the cap is clipped over and abuts against the abutment shoulder on the neck portion.

11. A plastic cartridge as claimed in claim 10 wherein the



underside of said top of the cap abuts against the upper annular face of the neck portion.

12. A plastic cartridge as claimed in either any one of the previous claim wherein the cap is welded to the cartridge barrel.

13. A prefilled syringe comprising a plastic cartridge as claimed in claim 4 or any of claims 5 to 12 when appended to claim 4 filled with an injectable medium, a finger grip attached to the cartridge barrel, a plunger rod adapted to cooperate with said stopper located in the bottom end of the cartridge barrel and a double sided hypodermic needle attached to the cap and adapted to puncture the relatively thin central portion of the top of the cap whereby following the puncture of the central portion of the cap by the reverse end of the double sided needle application of a force against the plunger rod causes positive forward movement of the stopper in the cartridge barrel thus facilitating expression of the injectable medium through the hypodermic needle.

14. A method for manufacturing a plastic pre-filled syringe cartridge which comprises:-

- (i) injection moulding a cartridge barrel having a top end and a bottom end both of which are open in an aseptic environment;
- (ii) injection moulding a plastic cap having an integral central portion of relatively thin cross section which may be punctured by a double sided needle;
- (iii) introducing into the aseptic environment a pre-sterilized stopper;
- (iv) fitting the pre-sterilized stopper into the bottom end of the cartridge barrel in the aseptic environment;
- (v) aseptically filling the said cartridge with an injectable medium in said aseptic environment sealingly; and
- (vi) welding said cap to the top end of the cartridge barrel in the aseptic environment.



15. A method as claimed in claim 14 wherein there is additionally provided an overcap which is injection moulded in the aseptic environment and which is placed over the cap after the said cap has been sealingly attached to the top end of the cartridge barrel.

16. A plastic cartridge according to claim 1 substantially as hereinbefore described with reference to what is shown in the drawings.

17. A method according to claim 14 substantially as hereinbefore described.

DATED: 20 August, 1990

PHILLIPS ORMONDE & FITZPATRICK  
Attorneys for:  
ASTRA PHARMACEUTICALS PTY. LTD.

*David B Fitzpatrick*

8527W





11602/88

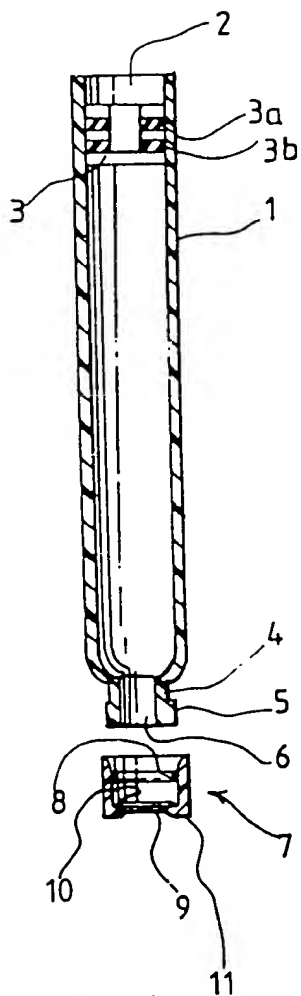


FIG 1

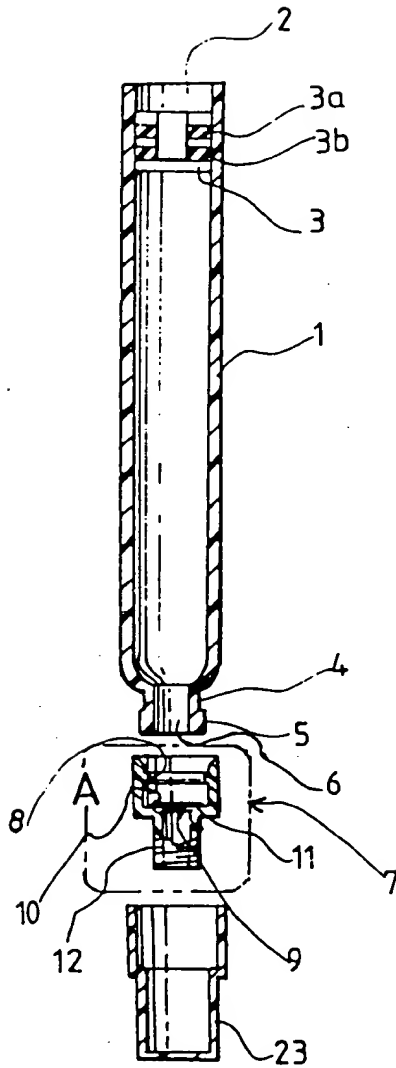


FIG 2

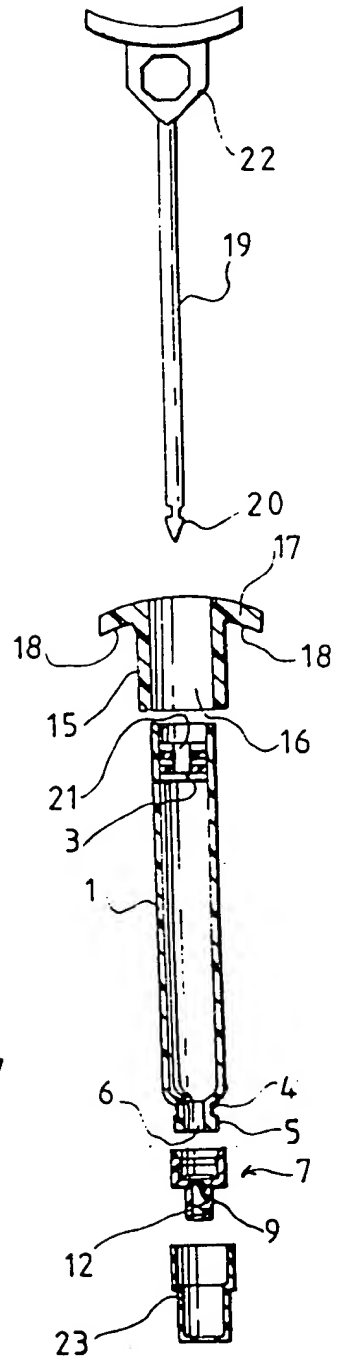
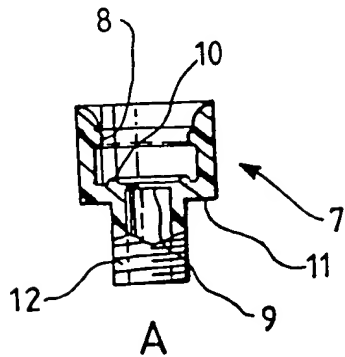


FIG 3

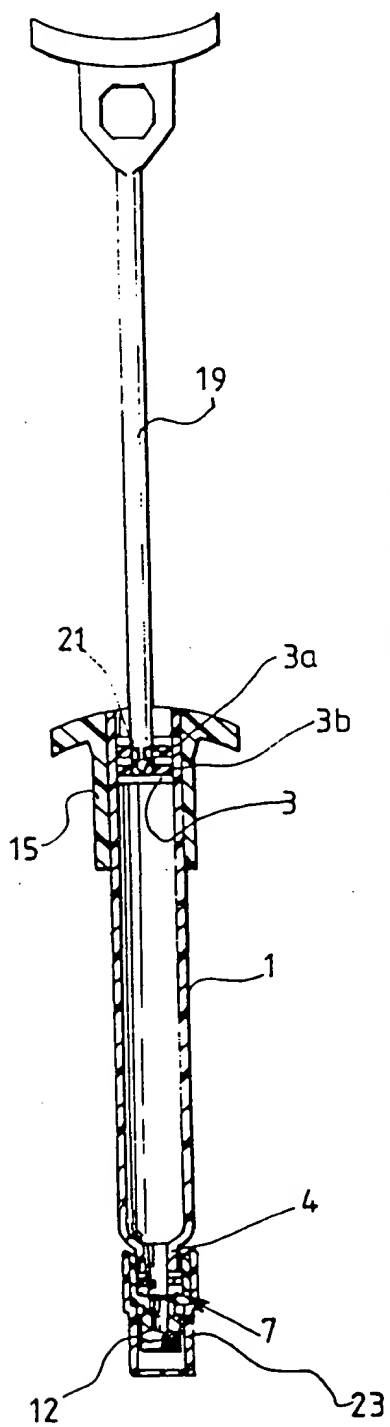


FIG 4

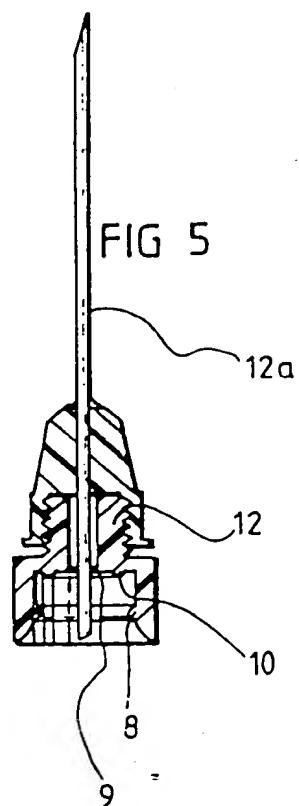


FIG 5

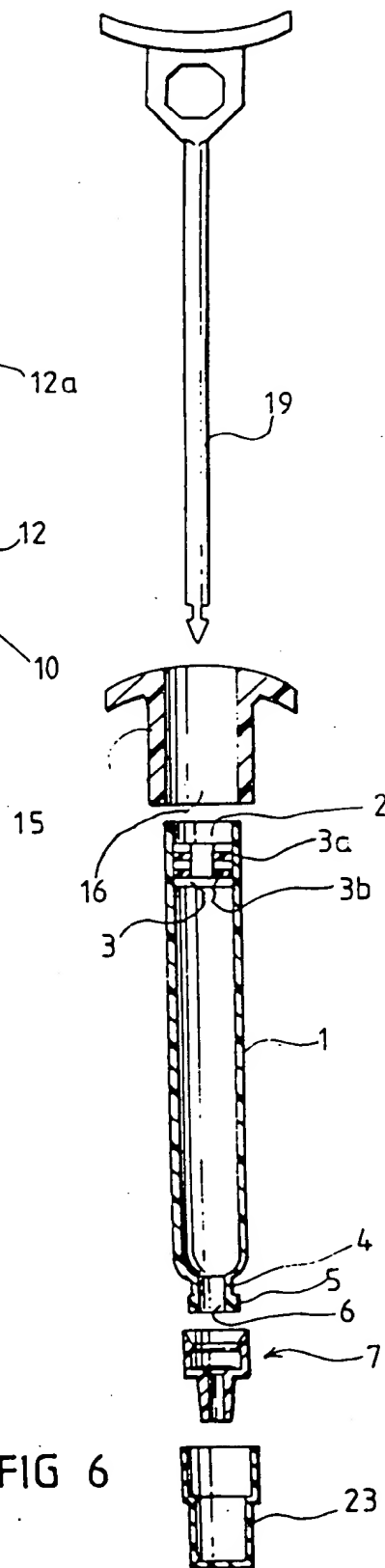


FIG 6

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☒ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☒ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**